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# A Survey: The Documentation of Manual Therapy

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A SURVEY: THE DOCUMENTATION OF MANUAL THERAPY

by

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An Independent Study

Submitted to the Graduate Faculty of the

Department of Physical Therapy

School of Medicine

University of North Dakota

in partial fulfillment of the requirements

for the degree of

Master of Physical Therapy

Grand Forks, North Dakota

May


1995



This Independent Study, submitted by Kimo Danielsen in partial fulfillment of the requirements for the Degree of Master of Physical Therapy from the University of North Dakota, has been read by the Faculty Preceptor, Advisor, and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

  
(Faculty Preceptor)

  
(Graduate School Advisor)

  
(Chairperson, Physical Therapy)

PERMISSION

Title                    A Survey: The Documentation of Manual Therapy

Department            Physical Therapy

Degree                Master of Physical Therapy

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Kimo Danielson

Date

3/24/45



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"I can do everything through Him who gives me strength." Philippians 4:13

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## ABSTRACT

Manual therapy, though clinically valuable, lacks published research to support efficacy. The purpose of this project was to survey therapists in the U.S. who use manual therapy in their clinical practice. Methods: All orthopedic clinical specialists (OCS) in the United States (n=325) as recognized by the American Physical Therapy Association's 1993 Directory of Clinical Specialists were sent a survey that contained questions regarding demographics, frequency of documentation, and items included in documentation. The information gained through the survey questions were analyzed for descriptive trends. Results: There was a 45% response rate. Majority of the respondents indicated they were male, worked in a private practice or outpatient setting, and chose Maitland as a theoretical construct. Discussion/Conclusion: The literature review served the purpose of identifying items that should be included in documentation. The survey displayed the lack of clear, thorough documentation in the clinical setting.

## CHAPTER 1

### INTRODUCTION

Because so much is spent on health care each year, the industry has come under increasing scrutiny by politicians, watchdog groups,...and the public at large.<sup>1</sup> There are at least forty different parties who may read and scrutinize our profession based on our documentation records.<sup>2</sup> These same parties, who may not understand what physical therapy is, and who have probably received minimal education regarding medical terminology, depend on the clarity, completeness, and effectiveness of our treatment techniques as expressed through our documentation.<sup>2</sup> If clinicians fail to provide their readers with what they depend upon, then they set themselves in a position where others may question their capabilities and the capabilities of their profession.<sup>2</sup> More and more claim reviewers are routinely judging reports based on its content<sup>2,3</sup> and whether or not it contains the basics: a clear problem statement, a description of action (treatment) to solve the problem, the results or progress from treatment, and the time it will take to remedy the problem.<sup>4</sup> As in all areas of physical therapy treatment and procedures, the basic criteria listed above should be included in

documentation and manual therapy techniques are no exception. With reference to manual therapy Lewit<sup>5</sup> states, "...in every case the technique used and it's precise location, side and direction are recorded. Without this documentation it is impossible to evaluate results, to learn from failure, or to deal with possible complications as described in the literature."

Physical therapists treat patients using manual therapy which can be described as a "hands on" technique that may consist of: massage, soft tissue mobilization, joint mobilization, joint range of motion, and/or manipulation. Though successful in the clinical setting, the description of treatment techniques in manual therapy often contains deficits in detail which in turn impair replicability,<sup>2,6-9</sup> dampen the strength of efficacy studies,<sup>2,6,7</sup> and may decrease third party reimbursement.<sup>2,9,10</sup> Most theoretical constructs of manual therapy have developed a standard assessment form as part of their treatment regime. But only Grieve<sup>11</sup> and Maitland<sup>12</sup> have specifically addressed the issue of documenting manual therapy techniques. In a conversation with Simunds, M.S., P.T., a North Dakota Blue Cross Blue Shield representative (June 1994), she stated, "an informal survey of local clinicians indicate that therapists bill manual therapy procedures under either therapeutic exercise or massage, because they do not have a specific charge for manual therapy. As such, the

therapists often do not document manual therapy techniques since it is not directly connected with payment."

Presently, poor documentation seems to be the common link for the decrease in replication of techniques, research proving efficacy, and third party reimbursement. The purpose of this study is to survey practitioners regarding their methodology for documenting manual therapy techniques. After the results are compiled, the intent is that a standard format will be generated in order to: provide the ground work for documenting when performing research efficacy studies, aid therapists with gaining reimbursement, and allow therapists a guideline to document effectively so treatment techniques can be replicated accurately.



## CHAPTER 2

### LITERATURE REVIEW

Based on a review of the literature, this researcher will discuss the documentation of manual therapy and it's relationship to efficacy studies, replication of treatment techniques, and reimbursement. For background purposes, the importance of documentation and the different formats used when documenting will also be discussed.

#### The Importance of Documentation

In the United States, documenting physical therapy procedures has evolved considerably. Some recent forms utilized have been: the problem oriented medical record (POMR), and the subjective-objective-assessment-plan note (SOAP note). The most recent and accepted form of documenting for physical therapy procedures is through the functional outcomes format.<sup>2,10,13,14</sup>

The POMR was developed to document patient procedures. Its design allowed health care professionals a systematic way of assessing the quality of care delivered to patients. With the POMR, the patient's problem list was located in the front of the chart and each discipline referred to it and planned their treatment(s) accordingly.<sup>9</sup> The SOAP format is an adaptation from the once popular

POMR.<sup>2,9</sup> Commonly in the United States, physical therapists utilize the SOAP format when recording in patient care notes. The SOAP format consists of subjective (S) and objective (O) portions, with an assessment (A), and then finally a statement of plan (P).<sup>9</sup>

From a patient satisfaction standpoint, however, SOAP notes gave a simplistic view point of the patient's functional status.<sup>2</sup> It assumed that improved physical capabilities, such as muscle strength, led directly to improved function, such as standing.<sup>2</sup> Documenting in this manner often left patients discontent because it warranted that they no longer needed therapy.<sup>2,10</sup> In other words, SOAP notes fell short in describing the patient as a whole functional person. Therefore, documentation which included functional outcomes became the most accepted form of documenting.<sup>2,10,13,14</sup>

The inclusion of functional outcomes takes the SOAP note a step further. As in the SOAP note, the functional outcome method generates valuable information by gathering pertinent details from the patients history. From the gathered history, the patient's functional limitations are identified. The history, limitations, therapist assessment, and problems are used to create functional outcome goals. These goals serve to establish a treatment plan that is tailored to the individual patient.<sup>13</sup> In the end, the patient, as well as third party payers, are

more satisfied with the physical therapy process.<sup>2,10,13,14</sup>

Documentation notes are imperative to the health care professional for many reasons. First, documentation notes record what the therapist does to manage the individual patient's case.<sup>2,9</sup> Through this, the rights of the therapist and patient are protected should any question occur in the future regarding the care provided to the patient. Documentation notes are considered legal documents, as are all parts of the medical record.<sup>9</sup>

Written notes also serve as a method of communicating with the patient's physician and other health professionals, including other therapists and assistants. The note communicates the results of the patient interview, objective measurements done, and the therapist's assessment of the patient's condition.<sup>2,9</sup> It outlines the therapist's and the patient's goals, as well as the plan for treatment. The goal of such communication is to provide consistency between the services provided by various health care professionals.<sup>9</sup> Good communication can serve many settings. In a rehabilitation center, school setting, or other settings using the rehabilitation team approach, the therapist's goals and the patient's level of function can be communicated to the other professionals involved in the patient's care.<sup>9</sup> Professionals providing services after the patient is discharged from one therapist's care may find that the therapist's notes can be very valuable

in providing good follow-up treatment.<sup>9</sup>

Another reason is that third party payers, such as medicare reviewers and representatives from insurance companies, make decisions about reimbursement based on therapy notes.<sup>2,3,6,9,10</sup> These decisions can be greatly influenced by the quality and completeness of the note.

Documentation also functions within the hospital and other types of facilities where patient charts are reviewed. Decisions on whether the patient is ready to be discharged are based, in part, upon the notes written by the therapist.<sup>9</sup>

Documenting consistently helps the therapist organize the thought processes involved in patient care.<sup>2,9</sup> By thinking in an organized manner, the therapist can better make decisions regarding patient care; thus, the functional outcome format provides an excellent method for structured thinking.

Documentation can be used for quality assurance purposes.<sup>2,9,10</sup> Certain criteria are set to indicate whether quality care is occurring. Within a limited time frame, the notes from all patients with a certain diagnosis can be assessed to see whether the pre-set criteria have been met.<sup>9,10</sup>

Thorough documentation enables research. As with quality assurance, certain criteria are initially set for the type of patient to be included, data to be taken, and

so forth. Data can then be gathered and conclusions drawn about the type of patients and/or the type of treatment provided.<sup>9,10</sup>

### Efficacy of Manual Therapy

As stated previously, published studies are necessary to provide the scientific proof that manual therapy is an effective form of treatment. DiFabio<sup>8</sup> addressed the eligibility requirements needed in a manual therapy research design. The criteria include: randomization, a blind outcome assessment, specific criteria for selecting subjects, a description of the intervention, statistical analysis, and statistical power. A study that contains all of these elements and supportive results of manual therapy published in a peer-reviewed journal would definitely provide power to manual therapy in the health care profession. In his study, DiFabio<sup>8</sup> reviewed 146 publications on manual therapy, and found that only 14 met the above criteria. Ironically, only 10 out of the 14 publications contained accurate descriptions of the treatment procedures. Currently, there are limited studies published which explore the efficacy of manual therapy. Several studies have attempted this; however each demonstrated problems with design.<sup>7,8,15-17</sup> As stated by Fitzgerald and associates<sup>6</sup>, "Many barriers exist that make it difficult to design experimental studies that examine the effectiveness of manual therapy. The same barriers

interfere with the production of case reports and all forms of clinical documentation".

Sloop et al<sup>15</sup> studied 39 patients with chronic neck pain. In the study, 21 of the subjects received an injection of diazepam and received 1 treatment of cervical spine manipulation. The other 18 subjects received an injection of diazepam without the cervical manipulation. The findings of the study revealed no significant therapeutic differences when comparing the manipulation coupled with diazepam to the diazepam injection alone. The outcomes, with the exception of one, had no correlation with any positive findings in the patients' histories or examinations. Sloop and associates acknowledged the difficulty of the experimental design and the lack of standardization of the manipulation techniques. They concluded on the basis of their experience and review of the literature that the value of a single manipulation to the cervical spine had not been established. They also promoted the need for better documenting of treatment results.

Koes et al<sup>16</sup> conducted a blinded review of spinal manipulation and mobilization for back and neck pain. The purpose of the study was to assess the efficacy of spinal manipulation for back and neck pain. The study, which consisted of 35 trials, compared spinal manipulation to other treatment procedures. The results of the study

revealed that only 51% of the trials favored manipulation as opposed to the other groups. Because the experiment contained poor design quality and demonstrated minimal support in favor of manipulation, the experimenters suggested the need for further study to substantiate the efficacy of manipulation.

In another study, Koes et al<sup>17</sup> compared the effectiveness of manual therapy to physical therapy and to the prescription of a general practitioner. Each of the 256 patients suffered from nonspecific back or neck complaints. Of the 256 patients, 65 were assigned to receive manual therapy, 66 physiotherapy, 61 treatment by the general practitioner, and 64 to receive placebo. Manual therapy consisted of both manipulation and mobilization. Physiotherapy consisted of exercise, massage, modalities, and no mobilization or manipulation. The general practitioner's treatment consisted of medicine, posture advice, participation in sports, home exercise, and other modalities. The placebo consisted of a physical exam, detuned shortwave, and detuned ultrasound. Each group received treatment two times a week for six weeks. In midstudy several subjects contaminated the study by switching groups. The examiners allowed the subjects to switch groups because they felt that some of the patients needed care that was not being offered in their assigned group. Although the study was sacrificed by this, Koes

and associates<sup>17</sup> maintain that switching was allowed on the basis of ethics. The results of this study demonstrated that patients treated with manipulation and physiotherapy experienced better outcomes at the six and 12 month follow-up than those in the other groups. However, the investigators reported that many patients received additional manipulative therapy or other co-interventions during the nine months after the intervention period. In addition, the study failed to mention how or the types of manipulations delivered, and the physiotherapy treatment parameters.

Hadler and associates<sup>7</sup> sought to find any significant differences in outcome between patients who received manipulation verses mobilization for low back pain treatment. The subjects were separated into two strata (1-2 weeks or 2-4 weeks) according to the length of time the patients suffered from back pain. A significant difference between manipulation and mobilization surfaced in the 2-4 week stratum. Patients who received manipulation reported a 50% reduction of signs and symptoms more rapidly than those who were treated with mobilization. Although the results seemed favorable for manipulation, the investigators cautioned against making generalizations from their findings, as they screened their subjects thoroughly prior to acceptance and they used only one type of manipulation. Hadler et al<sup>7</sup> demanded further study



to demonstrate the efficacy of such techniques.

The above studies attempted to provide the proof of efficacy for manual therapy techniques. However, the studies were limited because there was either a lack of standardization, poor design quality, or contamination. Efficacy studies are needed for manual therapy and clear documentation can provide a good base for the study of outcomes.<sup>18,19</sup> Outcome/case studies will assist in building the foundation for the sound research needed to prove manual therapy efficacy.

#### Replication of Techniques

Clinically, the best part of manual therapy is it's timeliness. Patients receiving manual therapy as part of their treatment regime show improvements quicker than those not receiving manual therapy.<sup>20</sup> But as stated above, timeliness is not the only concern. Thorough documentation in the clinic is needed to allow for replicability of technique, which can then serve research to provide the published proof that manual therapy works.

In the case of absence from the clinic, a good SOAP note can help a therapist communicate with other therapists or assistants who may provide substitute care for his or her patients during the absence.<sup>2,9</sup> There are many schools of thought regarding manual therapy documentation, and actual techniques of application can vary between individuals. Presently, all accredited physical therapy

programs in the U.S. require that some form of manual therapy/mobilization procedure be taught as part of the curriculum.<sup>21</sup> Because not all therapists receive the same training, documentation and technique application may differ.

Grieve<sup>11</sup> stated that accurate, complete, and precise recording of treatment procedures are necessary. When documenting each treatment session, he suggests including: technique used, grade, vertebral level(s) treated, number of times, effects during application, reminders for next attendance, patient's assessment of symptoms, and the therapist's assessment of signs. When applying traction, he recommends including: position and support given to patient, angle of pull, segment, force, duration, whether sustained, intermittent, rhythmic, or manipulative, periods of pull and rest, and the effects (see figure 1).

Maitland<sup>12</sup> recommends including several items during each treatment period. Subjectively, he recommends keeping a record of what the patient states as the result of the previous treatment. Objectively, he recommends documenting what the therapist views as changes in signs and symptoms from the last session. These symptoms are noted as asterisked signs and they should be reviewed at each treatment session. A statement of plan should include the technique used and the reason. Any present pain should also be noted. The actual treatment should be described

by the techniques and grades used, the level and number of times it was performed, and the effect it had while being performed. Maitland also suggests the therapist leave notes to serve as reminders for the following session and a statement with reasons regarding any changes in treatment.

Although various items of technique application are listed in different manual therapy texts<sup>5,22-26</sup>, there are minimal promotions or suggestions that these items should be included in documentation in order to increase replicability.

#### Reimbursement

Another important aspect for physical therapy clinicians is in the area of reimbursement. As stated previously, more and more health care providers are being denied reimbursement because of poor documentation.<sup>2,3,10</sup> When Simunds (per oral communication in June 1994) reviews a documentation record for granting reimbursement, she screens for the following items: First, she ensures that the note includes a patient goal. Simunds feels that the patient should be the center of the physical therapy treatment, and therefore should have an active involvement with the determination of these goals. Since she expects the patient to take an active role in his/her care, a list of expected functional outcomes, a home program and some form of patient education should be included. Second,

Simunds ensures that there is a clear problem statement and an appropriate treatment plan to correspond with it. The final item she expects to be included is timeliness. Timeliness meaning, "Are the expected outcomes being met in the time stated?" and if not, then "What is being done so that the outcomes are being met?" In other words, if a patient is being seen daily for 3 months, has been receiving the same treatment in that time, and is showing no improvement, then she expects to see a change in the treatment plan.

From the previous sections, it is understandable to see that there is a need for clinicians to document their findings consistently. Dana<sup>19</sup> stated, "The concept of writing logical justification is not new; it is as old as medicine. Yet, its application by busy practitioners became solely neglected over the years, and those of us who review charts continue to see evidence of poor documentation." Dana<sup>19</sup> suggests that the most promising approach to improving quality is the study of outcomes. Dana<sup>19</sup> offers two options to relieve the tension between the medical profession and the insurance industry: the first is better communication and the second is the publication of well designed outcome studies.

Lack of consistent documentation impairs researchers from performing studies that further support the use of manual therapy. Defining clear techniques of application

are crucial in designing efficacy studies. The documenting of such techniques will provide the foundation for research guidelines, allow for replicability of treatment, and possibly assist with third party reimbursement. The purpose of this study is to survey practitioners regarding their methodology for documenting manual therapy techniques.

After compiling the results, it is hoped that a consistent format will emerge, which will generate documentation guidelines for clinical practices.

## CHAPTER 3

### METHODS

A petition (see Appendix) was sent to the Institutional Review Board (IRB) for approval of this independent study. The petition gave a description of the subjects, development of the survey, procedures, benefits, and risks. A copy of the cover letter and survey accompanied the petition. Before approving the independent study, the IRB requested a statement of "no obligation and no prejudice against those declining to complete the survey" be included in the cover letter. The revision was made and the petition was approved. Three weeks after the initial mailing, a second petition was sent to the IRB for the approval of a follow-up mailing. The second mailing served two purposes: the first, a reminder to those who had not returned the survey to please do so, and the second, a thank you note to those who had returned the survey. The IRB approved the petition.

### Subjects

Three hundred twenty-five physical therapists recognized by the American Physical Therapy Association (APTA) as orthopedic clinical specialists (OCS) were

selected to receive the survey. All 325 OCS were chosen with the assumption that the OCS received a greater than average amount of knowledge in orthopedics, and therefore utilized manual therapy techniques accurately and on a regular basis. The ages of the subjects were expected to be between 22 years and 65 years of age. The names and addresses of these specialists were obtained from the APTA 1993 Directory of Clinical Specialists.

#### Survey Development

A review of the current literature was completed to determine controversial questions surrounding manual therapy documentation. The literature cited the lack of clear documentation as the largest limitation of efficacy studies surrounding the use of manual therapy. The survey questions were developed to address these controversies. The survey contained questions on demographics, frequency of documentation, and items included in documentation. The four-point scale question compiled the recommendations of Grieve and Maitland. This question was used to evaluate the items necessary to replicate manual therapy techniques. The open ended case scenario was included to evaluate the items that therapist reported in documentation as compared to the items recommended for both replication of techniques and reimbursement.

### Procedure

A survey was mailed to each of the therapists. Each OCS was sent an envelope that held a cover letter, the survey, and a self-addressed, stamped, return envelope. Approximately three weeks following the initial mailing, a reminder/thank you postcard was mailed. Each survey was assigned a reference number in the order returned to replace surname identity and to insure therapist confidentiality. The information from each of the survey questions was entered onto the SPSSX software for the generation of statistical frequencies. The frequencies were analyzed for descriptive trends such as: the type of practice setting, the number of years practicing both general and manual therapy, the number of manual therapy courses attended, gender, where techniques were learned, the theoretical construct for techniques used, the documentation requirement for the type of facility, the frequency of reporting the items recommended by Maitland and Grieve, and the items the therapist reported for the replication of techniques and reimbursement.

The suggestions in texts by Grieve and Maitland set an ideal standard for documenting manual therapy techniques. As mentioned previously, the 14 items contained in the four-point scale were recommendations taken from these texts. The survey requested that the therapist choose the points (1-Never, 2-Occasionally, 3-Frequently, or



4-Always) that best described their frequency of including the given items when documenting for manual therapy procedures. Since Grieve and Maitland promoted "always" including these items, four points were assigned to each, which computed an ideal (total) score of 56. In order to establish how therapists compared to the ideal, the therapists who listed Grieve and/or Maitland as a theoretical construct were identified. These therapist's scores were then computed and compared to the ideal. Points were also summed for the other groups in order to identify whether any trends occurred with the other chosen theoretical constructs. A one-way ANOVA and a Kruskal Wallis statistical test were used to determine whether any significant differences occurred between the groups.

## CHAPTER 4

### RESULTS

One hundred forty-five out of 325 OCS responded to the survey. The postal service returned three surveys because of an expired forwarding time. One OCS stated, per phone call, that he received the reminder postcard, but not the survey. Another OCS requested, per phone call, a second survey because he lost the initial one. A second survey was mailed to both of these therapists. Deleting the three OCS whose surveys were returned, a response rate of 45% (145/322) was computed.

#### Subjects

From the survey question requesting gender, 72 (49.7%) OCS indicated they were male, 68 (46.9%) OCS indicated they were female, and five (3.4%) OCS chose not to respond.

#### Facility

The survey asked the OCS to indicate the type of facility in which they worked. Sixty-five (44.8%) OCS wrote that they worked in a private practice, 54 (37.2%) in an outpatient center/clinic, 10 (6.9%) in a hospital, 6 (4.1%) in a rehab setting, 5 (3.4%) in an academic

institution, and 2 (1.4%) in a medical center. There was 1 (.7%) in a sports medicine/spine center, 1 (.7%) other, and 1 (.7%) with no response (see Table 1).

Table 1. Type of Facility in which OCS Practice (n=145)		
Setting	Frequency	Percent (%)
private practice	65	44.8
outpatient center/clinic	54	37.2
hospital	10	6.9
rehab	6	4.1
academic institution	5	3.4
medical center	2	1.4
sports/spine center	1	.7
other	1	.7
no response	1	.7

### Experience

The respondents gave a range of 1-40 years of general experience and a range of 2-23 years of manual therapy experience. Because extreme scores altered the mean scores for both general and manual years of experience, median scores were used. The median scores for general experience and manual experience were 13 years and 11 years, respectively.

The frequencies indicated that the OCS attended a range of 0-99 courses on manual therapy, with a median of 10 courses.

The survey responses demonstrated that majority of the OCS learned their manual therapy techniques through continuing education courses, on the job, in school, and by other means. The other means in which the OCS learned these techniques included residency programs, teaching, study groups, and/or independent reading of manual therapy texts. (Table 2.)

Table 2. Means by which OCS Learned Manual Techniques		
Means	Frequency	Percent (%)
continuing education	132/145	91.0
on the job	114/145	78.6
school	80/145	55.2
other*	40/145	27.6

\*residency programs, study groups, teaching, and/or independent reading of manual therapy texts

### Theoretical Construct

The most frequently chosen theoretical constructs were Maitland 113/145 (77.9%), Cyriax 91/145 (62.8%), Paris 90/145 (62.1%), Kaltenborn 88/145 (60.7%), and Grimsby 48/145 (33.1%). Some less frequent theoretical constructs (< 30%) for performing manual therapy techniques were: Grieve, Saunders, Strain/Counterstrain, McKenzie, Osteopathic, and Muscle energy.

The survey requested that the OCS indicate the number of times per day they used manual therapy techniques. The survey gave the following choices: 1-5 times per day, 6-10 times per day, 11-15 times per day, and 16 or more times per day. Twenty-two of the 145 respondents (15.2%) estimated that they used manual therapy techniques 1-5 times per day, 48 (33.1%) 6-10 times per day, 39 (26.9%) 11-15 times per day, and 34 (23.4%) 16 or more times per day. Two respondents (1.4%) chose not to answer the question.

### Documentation

When questioned on the required frequency of documenting in the inpatient setting, majority of the respondents 118/145 (81.4%) chose not applicable, because most of the respondents worked in some sort of outpatient setting. The most frequent documentation requirement for the outpatient setting 101/145 (69.7%) was in each session

followed by at least once daily 20/145 (13.8%).

Only 95 out of 145 therapists attempted to answer the open ended case scenario. Many indicated that they did not understand the way the question was presented. Because of this, the frequencies will not be listed.

The generated frequencies for the four point scale question found that only 1/145 (.7%) scored a 53 out of a possible 56 points. This score was the highest among the surveyed therapists. The most frequent score was a 39 out of 56. Eleven out of 145 (7.6%) therapists scored a 39 out of 56 points. The scores ranged from a 21/56 to 53/56.

The one way ANOVA and Kruskal-Wallis tests analyzed the three groups for any significant differences. The three groups consisted of therapists who chose: both Maitland and Grieve (group 1), either Maitland or Grieve (group 2), or neither Maitland nor Grieve (group 3). Group 1 contained 32 therapists (22.1%), group 2 contained 83 therapists (57.2%), group 3 contained 27 therapists (18.6%), and three of the cases were missing. The ANOVA found no significant differences among the groups with an F-ratio of 1.29 and an F-probability of .278. The Kruskal-Wallis also found no significance among the groups.



## CHAPTER 5

### DISCUSSION

In conjunction with Rothstein's<sup>18</sup> encouragement for more studies to support the use of manual therapy, this study attempted to generate specific guidelines for documentation. The guidelines could serve for improved documentation, which could lead to case/outcome studies.<sup>18</sup> Consistent replication of techniques through case/outcome studies would provide a basis for much needed efficacy studies. All of these would eventually lead to better quality care for patients and satisfaction for third party payers.<sup>10,19</sup>

A literature review established the guidelines for documentation, and the survey found demographic information such as gender, type of facility, years experience, theoretical construct, etc. The guidelines used for documenting manual therapy techniques should include a complete description of the technique and how it was delivered, along with the reason it was used, and the results gained (see Figure 1).

Figure 1.-Ideal for Documenting

- position of the patient
- technique used
- grade (s)
- duration (time)
- # of times performed per procedure
- direction of force
- vertebral level
- justification for technique
- support given to patient (bolsters, pillows, etc.)
- PT hand position
- patient's response
- patient's assessment of symptoms
- changes in symptoms from previous session
- signs that should be reviewed each session
- patient goal
- a list of expected functional outcomes
- a home program and some form of patient education
- a clear problem statement and an appropriate treatment
- timeliness

The survey generated unexpected responses to the question of gender. Nationally, females represent approximately 76% of physical therapists, while 24% are male. However, nearly 50% of the survey respondents were male, while 47% were female. The gender difference is significantly different in comparison to the national average.

The majority of the therapists indicated that they worked in a private practice (44.8%) or in an outpatient center (37.2%). In the United States, most private practices serve mainly on an outpatient basis; thus individual therapists may have approached the question differently. A few of the therapists listed more than one answer. In those cases, the investigator chose the type of facility that was listed first.

Responses to gender and type of facility raised questions that remain unanswered. Are males more apt to practice in outpatient/private practice clinics? Are males more driven toward orthopedics or the gaining of the "specialist" status? This study is not equipped to make assumptions regarding these questions. Individual therapists should examine themselves for the answers.

Open ended questions asked therapists to indicate their general and manual years of experience to the nearest whole year. Although the questions were separate, some of the therapists may have combined their general and manual

years experience. This would have caused the overall frequencies to be altered by the extreme scores. Also regarding experience, the survey asked therapists to indicate the number of manual therapy courses that they attended. Some returned surveys indicated that therapists attended more than 100, 200, 300, and even 400 courses. Based on the responses of these particular surveys, the investigator questions whether or not therapists were listing the hours or the actual number of manual therapy courses they attended. If a survey contained a response of 100 or more courses, the investigator assigned a score of 99.

The question requesting the means by which the therapists learned their manual therapy techniques indicated that 91% learned through continuing education courses. Therapist also learned through work, study groups, and even independent reading. This finding displays physical therapists' desire to seek more information to better prepare themselves in the clinical setting. Gaining knowledge through continuing education courses and through other means broadens therapists understanding and skills to better serve patients. It may have been helpful to request that therapists chose one area that best described where they learned majority of their techniques. Because some of the therapist listed more than one, it was difficult to determine where individual therapists learned the

majority of their techniques.

The survey highlighted popular theoretical constructs among the OCS. Nearly 80% of the respondents chose Maitland as a theoretical construct. The irony of this finding arises when the theoretical construct was coupled with the four-point scale survey question. This question asked therapists to choose the points that best described how often they included certain items when documenting. These items came directly from Grieve's and Maitland's text on manual therapy. As stated previously, both Grieve and Maitland recommend always including these items in documentation establishing a total score of 56 points. The actual scores ranged from 21/56 to 53/56. Although nearly 80% chose Maitland as a theoretical construct, very few of these therapists kept written notes according to the recommendations set forth in Maitland's text.

An ANOVA and Kruskal-Wallis statistical test was used to compare the theoretical construct to the documentation score. These tests found no significant differences among the groups. The ANOVA found a significant difference in the group's homogeneity of variance and therefore, the Kruskal-Wallis test was used. It should be noted that the total points from the four point scale may have been altered because therapists were self reporting.

Few studies, if any, are flawless and this survey is no exception. However, this study found that the experts

in the field of orthopedics and manual therapy were found to be deficient in their documentation when compared to a common standard. Based on this finding, one might wonder about the success rate of reimbursement for these therapists and the inter-therapist continuum of care in these particular facilities. This survey supports the literature in that therapists, even clinical specialists, do not document as they should. Because of this, the physical therapy profession faces problems when attempting to prove scientifically that the manual techniques rendered are effective.

As with all surveys, open ended questions contain large amounts of variability and require time and thought.

Ninety-five therapists attempted to respond to the case scenario. Because the responses among these 95 therapists varied from writing the letters S and O to giving a full evaluation, the investigator deleted it from analysis. Future surveys may find it more beneficial to request that therapists attach a sample, initial evaluation that contains the description of manual therapy techniques. From this, a checklist could be made of the items included and the results could be analyzed for trends.

## CHAPTER 6

### CONCLUSION

This investigator concludes that the literature review served the purpose of identifying items that therapists should include in documentation for manual therapy. The survey drew out interesting demographic information as well as pointed out the potential shortcomings of therapists' written notes. Including the items given may provide a good documentation base for replicating techniques for case/outcome studies which will lead to efficacy studies and eventually assist with third party reimbursement. Most importantly, good record keeping of techniques and replication of treatment would lead to better quality care for patients.

The survey displayed the lack of clear, thorough documentation in the clinical setting. No matter what the setting, therapists must remember and take the time to record the descriptions of their techniques, how and why it was used and the results.

Additional revision to the survey would have strengthened its results and statistical power. The survey could have been sampled by several therapists on a trial basis prior to its distribution. This would have allowed

the survey to be critiqued and revised more objectively. Future studies could assess documentation by means of a random chart audit. The findings could then be applied to the statistical tests.

Hopefully the literature review and the findings of the survey will motivate readers to document thoroughly, and clearly in their written notes.



APPENDIX A  
IRB PETITION

☒ EXPEDITED REVIEW REQUESTED UNDER ITEM 9 (NUMBER(S)) OF HHS REGULATIONS  
☐ EXEMPT REVIEW REQUESTED UNDER ITEM \_\_\_\_\_ (NUMBER(S)) OF HHS REGULATIONS

UNIVERSITY OF NORTH DAKOTA  
HUMAN SUBJECTS REVIEW FORM  
FOR NEW PROJECTS OR PROCEDURAL REVISIONS TO APPROVED  
PROJECTS INVOLVING HUMAN SUBJECTS

PRINCIPAL  
INVESTIGATOR: Kimo Danielson TELEPHONE: (701) 772-6385 DATE: 8-5-94  
ADDRESS TO WHICH NOTICE OF APPROVAL SHOULD BE SENT: 3717 Berkeley Dr. #7 Grand Forks, ND  
SCHOOL/COLLEGE: UND DEPARTMENT: Physical Therapy PROPOSED PROJECT DATES: 9/1/94-4/1/95  
PROJECT TITLE: A Survey: Documentation of Manual Therapy

FUNDING AGENCIES (IF APPLICABLE): \_\_\_\_\_

TYPE OF PROJECT: \_\_\_\_\_ NEW PROJECT \_\_\_\_\_ CONTINUATION \_\_\_\_\_ RENEWAL \_\_\_\_\_ DISSERTATION OR  
THESIS RESEARCH ☒ STUDENT RESEARCH PROJECT  
\_\_\_\_\_ CHANGE IN PROCEDURE FOR A PREVIOUSLY APPROVED PROJECT

DISSERTATION/THESIS ADVISER, OR STUDENT ADVISER: Erin Simunds M.S., P.T.

PROPOSED PROJECT: \_\_\_\_\_ INVOLVES NEW DRUGS (IND) \_\_\_\_\_ INVOLVES NON-APPROVED USE OF DRUG \_\_\_\_\_ INVOLVES A COOPERATING  
INSTITUTION

IF ANY OF YOUR SUBJECTS FALL IN ANY OF THE FOLLOWING CLASSIFICATIONS, PLEASE INDICATE THE CLASSIFICATION(S):

\_\_\_\_\_ MINORS (<18 YEARS) \_\_\_\_\_ PREGNANT WOMEN \_\_\_\_\_ MENTALLY DISABLED \_\_\_\_\_ FETUSES \_\_\_\_\_ MENTALLY RETARDED  
\_\_\_\_\_ PRISONERS \_\_\_\_\_ ABORTUSES \_\_\_\_\_ UND STUDENTS (>18 YEARS)

IF YOUR PROJECT INVOLVES ANY HUMAN TISSUE, BODY FLUIDS, PATHOLOGICAL SPECIMENS, DONATED ORGANS, FETAL MATERIAL, OR PLACENTAL  
MATERIALS, CHECK HERE \_\_\_\_\_

1. ABSTRACT: (LIMIT TO 200 WORDS OR LESS AND INCLUDE JUSTIFICATION OR NECESSITY FOR USING HUMAN SUBJECTS.)

With the rising demands of health care reform, the documentation of health care professionals is being scrutinized for methodology and justification. Documentation serves as the link of communication between health care professionals and many other interested parties (insurance companies, lawyers, workers compensation reviewers, etc.). Physical therapists (PT) often utilize manual therapy techniques as part of their treatment regime. Manual therapy (MT), though clinically valuable, lacks published research to support efficacy. In reviewing the literature, the lack of clear documentation seems to be the main hindrance in these efficacy studies. The purpose of this project is to survey PT's in the U.S. who use manual therapy in their clinical practice.

All PT's who are clinical specialists in orthopaedics as recognized by the American Physical Therapy Association (APTA), will be asked to participate in this survey. The survey will contain demographic information and questions in general areas of education, utilization, and documentation. All data will be collected aggregately and analyzed for descriptive trends. After compiling the results of this survey, it is hoped that a consistent format will emerge which will generate documentation guidelines for clinical practice and aid in setting the foundation of techniques for research in efficacy studies of MT.

PLEASE NOTE: Only information pertinent to your request to utilize human subjects in your project or activity should be included on this form. Where appropriate attach sections from your proposal (if seeking outside funding).

2. PROTOCOL: (Describe procedures to which humans will be subjected. Use additional pages if necessary.)

Subjects: Three-hundred twenty-five Physical therapist who are recognized by the APTA (per 1993 Directory of Certified Clinical Specialists in Physical Therapy) as Orthopaedic Clinical Specialist will receive the survey. The approximate ages of the therapists should range between 22 years and 65 years of age. Each survey will be assigned a reference number as it is returned to replace surname identity and to insure therapist confidentiality.

Survey development: A review of current literature was completed to determine controversial questions surrounding manual therapy documentation. The literature cites the lack of clear documentation as the largest limitation of efficacy studies surrounding the use of manual therapy. The survey questions were developed to address these controversies (Appendix A).  
Procedure: Each survey will be mailed with a self-addressed, stamped, return envelope included. A projected return date had been set for October 1, 1994, at which time all data will be collected aggregately and analyzed for descriptive trends.

Reference: Di Fabio RP. Efficacy of Manual Therapy. Phys Ther. 1992;72:853-864.

3. **BENEFITS:** (Describe the benefits to the individual or society.)

1. Help to set a standard for documenting manual therapy to increase accuracy of communication between therapists and other interested parties.
2. Increase consistency of treatment techniques in a clinical practice which will lead to a more rapid recovery of patients receiving manual therapy.
3. Generate a foundation of technique guidelines for use in research (particularly efficacy studies).

4. **RISKS:** (Describe the risks to the subject and precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes risks to the subject's dignity and self-respect, as well as psychological, emotional or behavioral risk. If data are collected which could prove harmful or embarrassing to the subject if associated with him or her, then describe the methods to be used to insure the confidentiality of data obtained, including plans for final disposition or destruction, debriefing procedures, etc.)

The potential risk for confidentiality has been addressed by assigning a reference number to each survey as it is returned. If any reference to the subject occurs in the study, this number will be used rather than surname information.

5. **CONSENT FORM:** A copy of the **CONSENT FORM** to be signed by the subject (if applicable) and/or any statement to be read to the subject should be attached to this form. If no **CONSENT FORM** is to be used, document the procedures to be used to assure that infringement upon the subject's rights will not occur.

Describe where signed consent forms will be kept and for what period of time.

No consent form is required, as the therapists' agreement to participate in the survey serves as a form of consent.

All surveys will be kept on file with the following for a period of two years:

Erin Simunds, M.S., P.T.  
Rm 146, Medical Science North  
Physical Therapy Department  
University of North Dakota

6. For **FULL IRB REVIEW** forward a signed original and thirteen (13) copies of this completed form, and where applicable, thirteen (13) copies of the proposed consent form, questionnaires, etc. and any supporting documentation to:

Office of Research & Program Development  
University of North Dakota  
Box 8138, University Station  
Grand Forks, North Dakota 58202

On campus, mail to: Office of Research & Program Development, Box 134, or drop it off at Room 101 Twamley Hall.

For **EXEMPT** or **EXPEDITED REVIEW** forward a signed original and a copy of the consent form, questionnaires, etc. and any supporting documentation to one of the addresses above.

-----

The policies and procedures on Use of Human Subjects of the University of North Dakota apply to all activities involving use of Human Subjects performed by personnel conducting such activities under the auspices of the University. No activities are to be initiated without prior review and approval as prescribed by the University's policies and procedures governing the use of human subjects.

**SIGNATURES:**

Kimo Danielson  
Principal Investigator  
Erin E. Simunds MS, P.T.  
Project Director or Student Adviser

DATE: August 5, 1994

DATE: 8/5/94

\_\_\_\_\_  
Training or Center Grant Director

DATE: \_\_\_\_\_

3717 Berkeley Drive #7  
Grand Forks, ND 58203  
(701)772-6385

Dear Physical Therapist,

My name is Kimo Danielsen and I am a Physical Therapy student at the University of North Dakota. As part of my fulfillment for my M.P.T. degree, I am required to conduct an independent project. The focus of my independent project is to survey therapists regarding their methodology for documenting manual therapy techniques. My goal is to generate a standard format of documentation which will facilitate consistency of treatment techniques in clinical practice and potentially assist in justifying these techniques for third-party reimbursement.

Your responses will be kept confidential as your survey will be assigned a reference number when it is returned. This number will be used if the data are referred to in the results. I would greatly appreciate it if you take the time to complete the enclosed survey and return it to me by October 1, 1994. A self-addressed, stamped envelope is enclosed for your convenience.

I would like to thank you for your time and effort.

Sincerely,

*Kimo Danielsen, S.P.T.*  
Kimo Danielsen, S.P.T.

## SURVEY

The following is an independent project focused at surveying therapists regarding their methodology for documenting manual therapy techniques. The goal of this survey is to generate a standard format of documentation which will facilitate consistency of treatment techniques in the clinic and potentially assist in justifying these techniques for third-party reimbursement.

Please complete:

Type of facility you work in: \_\_\_\_\_

Years Experience (to the nearest whole year): General: \_\_\_\_\_  
Manual Therapy: \_\_\_\_\_

Number of manual therapy courses you have taken: \_\_\_\_\_

Gender (circle one): Male Female

What were the setting(s) where you learned your manual techniques? (Please check all that apply.)

☐ school ☐ continuing education course(s)  
☐ on job ☐ other (please specify) \_\_\_\_\_

Which theoretical constructs represent the manual therapy techniques you use? (Please check all that apply.)

☐ Maitland ☐ Paris  
☐ Cyriax ☐ Greive  
☐ Grimsby ☐ Strain/Counterstrain  
☐ Kaltenborn ☐ Saunders  
☐ Others (please specify) \_\_\_\_\_

In your practice, estimate how many times per day you utilize manual therapy techniques. (Please check one.)

☐ 1-5 times/day  
☐ 6-10 times/day  
☐ 11-15 times/day  
☐ 16+ times/day

In your practice, how often is documentation required in the inpatient setting? (Please check one.)

☐ not applicable  
☐ at least once daily  
☐ weekly  
☐ every other session  
☐ each session  
☐ other (please specify) \_\_\_\_\_

In your practice, how often is documentation required in the outpatient setting? (Please check one.)

- ☐ not applicable  
☐ at least once daily  
☐ weekly  
☐ every other session  
☐ each session  
☐ other (please specify) \_\_\_\_\_

Using the 4-point scale below please grade the frequency of each of the items below as you use them when documenting for manual therapy in your practice.

1=Never                      2=Occasionally                      3=Frequently                      4=Always

- ☐ position of the patient  
☐ technique used  
☐ grade (s)  
☐ duration (time)  
☐ # of times performed per procedure  
☐ direction of force  
☐ vertebral level  
☐ justification for technique  
☐ support given to patient (bolsters, pillows, etc.)  
☐ PT hand position  
☐ patient's response  
☐ patient's assessment of symptoms  
☐ changes in symptoms from previous session  
☐ signs that should be reviewed each session  
☐ others (please specify with frequency) \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Additional Comments:



**Case Scenario:** The following is a patient referred to you for treatment. You use your manual therapy skills and your patient experiences some relief of signs and symptoms.

**History:** Patient is a 28-year-old male waiter who recalls onset occurring after colliding with another employee when attempting to exit through a swinging door. The collision occurred three days ago, while the patient was carrying an overhead tray on his right side. The patient recalls feeling a pop in his back. With minimal relief from NSAID's, the patients main complaints are: stiffness, mid-back pain that increases with inspiration, inability to sleep on his back, and inability to turn his trunk toward the left. X-rays were negative with no remarkable findings.

**Posture:** tilted and rotated to the right in sitting and standing; guarded and flexed in upper spine with rounded shoulders and forward head.

**Palpation:** tenderness at the level approximately equal to the inferior angle of the scapula.

**Thoracic range of motion:** flexion is minimally limited; extension, right and left lateral flexion, and right rotation are moderately limited; and left rotation is severely limited. Repeated movements cause no change in symptoms.

**Manual muscle test:** normal for upper and lower extremities.

**Neurologic status:** sensation and deep tendon reflexes intact throughout.

As in your clinical practice, create a documentation record of the above scenario. Write on the back of this sheet if necessary.

APPENDIX B  
IRB APPROVAL

UNIVERSITY OF NORTH DAKOTA'S  
INSTITUTIONAL REVIEW BOARD

DATE: August 5, 1994  
NAME: Kimo Danielsen DEPARTMENT/COLLEGE Physical Therapy  
PROJECT TITLE: A Survey: Documentation of Manual Therapy

The above referenced project was reviewed by a designated member for the University's Institutional Review Board on August 7, 1994 and the following action was taken:

- ☐ Project approved. EXPEDITED REVIEW NO. \_\_\_\_\_.  
Next scheduled review is on \_\_\_\_\_.
- ☐ Project approved. EXEMPT CATEGORY NO. \_\_\_\_\_. No periodic review scheduled unless so stated in REMARKS SECTION.
- ☒ Project approved PENDING receipt of corrections/additions in ORPD and approval by the IRB. This study may NOT be started UNTIL IRB approval has been received. (See REMARKS SECTION for further information.)
- ☐ Project approval deferred. This study may not be started until IRB approval has been received. (See REMARKS SECTION for further information.)
- ☐ Project denied.  
(See REMARKS SECTION for further information.)

REMARKS: Any changes in protocol or adverse occurrences in the course of the research project must be reported immediately to the IRB Chairman or ORPD.

- Letter to potential subjects needs sentence indicating that (a) they are under no obligation to participate and (b) no prejudice will occur if they do not complete survey.

cc: E. Simunds, Adviser

Michael J. Fenn 8/7/94  
Signature of Chairperson or designated IRB Member Date  
UND's Institutional Review Board

If the proposed project (clinical medical) is to be part of a research activity funded by a Federal Agency, a special assurance statement or a completed 596 Form may be required. Contact ORPD to obtain the required documents. (7/93)

3717 Berkeley Drive #7  
Grand Forks, ND 58203  
(701)772-6385

Dear Physical Therapist,

My name is Kimo Danielsen and I am a Physical Therapy student at the University of North Dakota. As part of my fulfillment for my M.P.T. degree, I am required to conduct an independent project. The focus of my independent project is to survey therapists regarding their methodology for documenting manual therapy techniques. My goal is to generate a standard format of documentation which will facilitate consistency of treatment techniques in clinical practice and potentially assist in justifying these techniques for third-party reimbursement.

Your responses will be kept confidential as your survey will be assigned a reference number when it is returned. This number will be used if the data are referred to in the results. You are under no obligation to complete this survey and no prejudice will occur if you do not. I would appreciate it, however, if you take the time to complete the enclosed survey and return it to me by October 1, 1994. A self-addressed, stamped envelope is enclosed for your convenience.

I would like to thank you for your time and effort.

Sincerely,

*Kimo Danielsen, SPT.*  
Kimo Danielsen, S.P.T.

UNIVERSITY OF NORTH DAKOTA'S  
INSTITUTIONAL REVIEW BOARD


DATE: August 9, 1994  
 NAME: Danielsen, Kimo DEPARTMENT/COLLEGE Physical Therapy  
 PROJECT TITLE: A Survey: Documentation of Manual Therapy

The above referenced project was reviewed by a designated member for the University's Institutional Review Board on August 10, 1994 and the following action was taken:

- ☒ Project approved. EXPEDITED REVIEW NO. 9.  
 Next scheduled review is on August 1995.
- ☐ Project approved. EXEMPT CATEGORY NO. \_\_\_\_\_. No periodic review scheduled unless so stated in REMARKS SECTION.
- ☐ Project approved PENDING receipt of corrections/additions in ORPD and approval by the IRB. This study may NOT be started UNTIL IRB approval has been received. (See REMARKS SECTION for further information.)
- ☐ Project approval deferred. This study may not be started until IRB approval has been received. (See REMARKS SECTION for further information.)
- ☐ Project denied.  
 (See REMARKS SECTION for further information.)

REMARKS: Any changes in protocol or adverse occurrences in the course of the research project must be reported immediately to the IRB Chairman or ORPD.

cc: E. Simunds, Adviser  
 Dean, Medical School

  
 Signature of Chairperson or designated IRB Member      Date 8/10/94  
 UND's Institutional Review Board

If the proposed project (clinical medical) is to be part of a research activity funded by a Federal Agency, a special assurance statement or a completed 596 Form may be required. Contact ORPD to obtain the required documents. (7/93)

APPENDIX C  
PROTOCOL CHANGE

September 26, 1994

Dear Institutional Review Board,

Approximately three weeks ago, I sent surveys to 325 different Orthopaedic Certified Specialists (as recognized by the American Physical Therapy Association in 1993) in the United States. As of 9/26/94, approximately 33% of the surveys were returned. In order to increase the data base for my study, I would like to send a follow-up postcard as a reminder to return the survey. The follow-up postcard would be sent to all 325 of the Orthopaedic Certified Specialists that received the survey. Attached is a sample of the follow-up postcard.

Thank you,

A handwritten signature in cursive script that reads "Kimo Danielsen". The signature is written in dark ink and is positioned above the printed name.

Kimo Danielsen

Sample of follow-up postcard

(front)

Dear Physical Therapist,

Approximately three weeks ago, you  
received a University of North Dakota  
Physical Therapy Survey on the  
Documentation of Manual Therapy.

If you haven't yet, please return the survey  
ASAP! For those who have returned the survey,  
thank you very much! If there are any  
questions regarding the survey or if you  
need another copy of the survey, please  
feel free to call me at (701)772-6385.

(back)

Department of Physical Therapy  
School of Medicine  
University of North Dakota  
PO Box 9037  
Grand Forks, ND 58202-9037



UNIVERSITY OF NORTH DAKOTA'S  
INSTITUTIONAL REVIEW BOARD

DATE: September 27, 1994

NAME: Kimo Danielsen DEPARTMENT/COLLEGE Physical Therapy

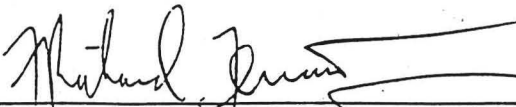
PROJECT TITLE: A Survey: Documentation of Manual Therapy (Protocol Change)

The above referenced project was reviewed by a designated member for the University's Institutional Review Board on 9/26/94 and the following action was taken:

- ☒ Project approved. EXPEDITED REVIEW NO. 9.  
Next scheduled review is on August 1995.
- ☐ Project approved. EXEMPT CATEGORY NO. \_\_\_\_\_. No periodic review scheduled unless so stated in REMARKS SECTION.
- ☐ Project approved PENDING receipt of corrections/additions in ORPD and approval by the IRB. This study may NOT be started UNTIL IRB approval has been received. (See REMARKS SECTION for further information.)
- ☐ Project approval deferred. This study may not be started until IRB approval has been received. (See REMARKS SECTION for further information.)
- ☐ Project denied.  
(See REMARKS SECTION for further information.)

REMARKS: Any changes in protocol or adverse occurrences in the course of the research project must be reported immediately to the IRB Chairman or ORPD.

cc: E. Simunds, Adviser  
Dean, Medical School

 9/26/94

Signature of Chairperson or designated IRB Member Date  
UND's Institutional Review Board

If the proposed project (clinical medical) is to be part of a research activity funded by a Federal Agency, a special assurance statement or a completed 596 Form may be required. Contact ORPD to obtain the required documents. (7/93)

## REFERENCES

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